1636

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	Arenas, Ernest et al.
Serial No.	:	09/980,913
Filing Date	:	May 21, 2002
Examiner	:	Gerald G. Leffers Jr.
Group Art Unit	:	1636
Entitled	:	Materials and Methods Relating to Neuronal Development

Suite 2400
1601 Market Street
Philadelphia, PA 19103
(215) 563-4100 (telephone)
(215) 563-4044 (facsimile)
Our File No. 0380-PO2709US0

Certification of Mailing Under 37 CFR §1.8(a)

I hereby certify that this correspondence is being deposited on January 6, 2004 with the United States Postal Service as first class mail in an envelope addressed to COMMISSIONER FOR PATENTS, P.O. Box 1450, Alexandria, VA 22313-1450.

Caren Burgoon

Caren Burgoon

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION UNDER 37 C.F.R. §1.144 FOR REVIEW AND WITHDRAWAL OF FINAL RESTRICTION REQUIRMENT

Dear Sir:

Applicants in the above-identified patent application, by their undersigned attorneys, hereby petition the Honorable Commissioner of Patents and Trademarks for review of the restriction requirement set forth in the Official Action dated March 19, 2003. Reconsideration of the requirement was requested in Applicant's response filed April 21, 2003. The

requirement was maintained and made final in the Official Action dated July 16, 2003.

Withdrawal of the aforementioned restriction requirement is respectfully requested for the reasons presented hereinbelow.

I. Statement of Relevant Facts

The instant application was filed under 35 U.S.C. §371, as a national stage application of PCT/EP00/03842.

In the International Search Report, mailed September 1, 2001, and in the IPER, mailed August 28, 2001, no objection based on lack of unity was made.

A Restriction Requirement was issued by the USPTO on March 19, 2003. This requirement identified seven Groups of inventions, considered to be separately patentable, as follows:

Group I - claims 1-12, 19-21, and 32-40, drawn to methods of inducing a dopaminergic neuronal fate for a neural stem cell, or neural progenitor cell, comprising expressing Nurr1 above basal levels in the neural stem cell or neural progenitor cell, and the dopaminergic neuronal cell produced thereby; as well as methods drawn to screening for a factor or factors that induce a dopaminergic fate in a neural stem or progenitor cell expressing Nurr1 above basal levels.

Group II - claims 13-15 and 41-43 drawn to a process of producing a medicament comprising a dopaminergic neuron and use of the medicament for transplantation into the brain of a subject.

Group III - claims 23-24, and 58 drawn to use of a dopaminergic neuron in methods of screening for an agent for use in treatment of a neurodegenerative disease, as well as drawn to a method directed towards using a dopaminergic neuron in methods of screening for compounds that enhance an ability

of the neuron to recover from or tolerate a toxic compound.

Group IV - claims 25-28, drawn to a method of formulating into a composition an agent that improves the ability of a dopaminergic receptor to recover from or tolerate a toxin and administration of the composition comprising such agent to an individual.

Group V - claims 29-31, drawn to a method of screening for a receptor or receptors for factors obtained from Type I astrocytes, comprising comparing neural stem and progenitor cells with or without expression of Nurr1, to identify the receptor(s).

Group VI - claims 48-51, drawn to methods of screening for a substance which modulates the ability of Type I astrocytes, or molecules obtained from such astrocytes, to induce a dopaminergic fate in neural stem or progenitor cells.

Group VII - claims 52-54, drawn administration to an individual of a composition that modulates the ability of a Type I astrocyte, or molecules produced therefrom, to induce a dopaminergic fate in a neuronal stem or progenitor cell.

According to the Examiner:

"The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT rule 13.1, because under PCT rule 13.2, they lack the same or corresponding technical feature for the following reasons: the special technical feature is the identification of a factor obtainable from a Type I astrocyte that can induce a neuronal stem or progenitor cell over expressing Nurr1 to a dopaminergic cell fate. With regard to the other groups, the dopaminergic cells or modulators of the inventions of the other groups could be obtained by alternative sources or by alternative methods. Moreover, the methods of the other groups comprise

additional special technical features not present in or required for the methods of Group I (e.g. administration of a medicament to an individual)."

A response to the restriction requirement, including election with traverse, was duly filed on April 21, 2003. In the traversal, it was pointed out that the special technical feature of all of the pending claims is the feature of having neuronal stem or progenitor cells over-expressing Nurr1 in the presence of Type I astrocyte factors. Applicants also noted that the Examiner did not apply Unity of Invention Standards in making the restriction requirement, and further that there was no lack of unity objection during the international stage of the application.

In the Official Action dated July 16, 2003, the Examiner withdrew certain claims from the elected group i.e. (claims 33 and 36), and cited U.S. Patent 6,284,539 as purportedly providing evidence that it was known in the art at the time of applicants' invention to obtain dopaminergic cells by induction of dopaminergic cell fate in neuronal precursor cells in response to increasing levels of expression of Nurr1 in the cells. The restriction requirement was made final.

II. Points for Review

This petition for withdrawal of the restriction requirement is based on the following points:

- The claims have unity of invention under the relevant PCT standards. No objection for lack of unity was made during the international phase. The same claimed subject matter was found to lack unity by the United States Examiner.
- The Examiner did not apply the correct standard when making the restriction requirement. The PCT provisions, and no other rules, should be applied when determining

whether the claims have unity of invention. In this case, the Examiner failed to correctly identify the unifying special technical feature of the invention, and improperly applied U.S. restriction practice in finding a lack of unity of invention.

- The Examiner made the restriction requirement final after changing the claim groupings. This was procedurally improper.

1. The Present Claims Have Unity of Invention Under the Appropriate PCT Standard

a. PCT Provisions

The present application is the US National Phase of international application PCT/EP00/03842, filed under the PCT and published as WO 00/66713.

Art 27(1) PCT states that:

> "No national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations."

The USPTO must therefore apply the provisions of the PCT in determining whether the claims have unity of invention. The relevant provisions are as stated under Rule 13 PCT:

> "13.1 The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

13.2 Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

13.3 The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim."

No objection of lack of unity of invention was made during the International Phase. This was not the result of an oversight by the International Searching Authority. The claims are unified under the PCT rules (explained in detail below) and consequently there was no legal basis for the restriction requirement made during the National Phase.

b. The Present Claims Have Unity of Invention

Applying the PCT rules, claims must be considered to have unity of invention when they share at least one common or corresponding special technical feature. The 'special technical feature' is a technical feature that defines the contribution that the claimed inventions, considered as a whole, make over the prior art.

A new and surprising finding on which the present invention is based is that a factor or factors obtainable from

a Type 1 astrocyte of the ventral mesencephalon (VM) can be used to induce dopaminergic neuronal fate in a cell. The Office Action dated 16 July 2003 acknowledges that this concept is novel in the art (page 4, final paragraph). This finding underlies all the present claims, and provides the required common or corresponding special technical feature.

Claim 1 relates to a method of inducing dopaminergic fate in a cell, where the method includes contacting the cell with one or more factors obtainable from a Type 1 astrocyte of the ventral mesencephalon.

Claims in Groups I, II, III and IV all include the features of claim 1, because they are dependent on claim 1. Therefore, claims of Groups II, III and IV must by definition include the special technical features of Group I.

The claims in Groups V, VI and VII are not dependent on claim 1, but share the same or a corresponding special technical feature with claim 1.

The Group V claims (29, 30, 31) relate to a method of screening for a receptor for factors obtainable from Type I astrocytes of the VM. The finding that a factor or factors obtainable from a Type 1 astrocyte of the VM can be used to induce dopaminergic neuronal fate in a cell indicates that neural stem or progenitor cells expressing Nurr1 above basal levels express a receptor or receptors for such a factor or factors obtainable from the astrocytes. Such a receptor can be screened for by comparing cells that express Nurr1 above basal levels with cells that do not express Nurr1 above basal levels.

The Group V claims are united with Groups I-IV because the novelty and inventive step for all these claims arises from the same underlying contribution to the art, i.e. the finding that a factor or factors obtainable from a Type 1 astrocyte of the VM can be used to induce dopaminergic

neuronal fate in a cell.

The Group VI claims (48, 49, 50, 51) relate to a method of screening for a substance that modulates the ability of Type I astrocytes (or a molecule of such astrocytes) to induce dopaminergic fate. Again, this method shares unity of invention with the other claim groups because the underlying contribution to the art is the same. The Group VI claims are novel and inventive because it was not previously known or suggested that Type I astrocytes produce a factor that induces dopaminergic fate in neural stem or progenitor cells.

The Group VII claims (52, 53 and 54) are dependent on the Group VI claims and consequently a special technical feature must by definition be shared by Groups VI and VII, for the reasons explained above in relation to Groups I-IV.

Contrary to the Examiner's argument, additional features in Groups V, VI and VII cannot negate the special technical features that these claims share with the Group I claims.

In summary, claims of Groups I to VII are unified under the PCT unity of invention standard, because all the claims share the same or a corresponding special technical feature arising from the novel and inventive finding that a factor obtainable from a Type 1 astrocyte of the ventral mesencephalon induces dopaminergic neuronal fate in a neural stem or progenitor cell.

2. <u>The Examiner Applied The Wrong Standard in Determining Unity of Invention</u>

The Examiner failed to properly evaluate the claims under the rules for Unity of Invention, and further, improperly followed US restriction practice in determining patentable distinctness.

As stated in MPEP 1893.03(d):

> When making a lack of unity of invention requirement, the Examiner must (1) list the different groups of claims and (2) explain why each group lacks unity with each other group (i.e., why there is no single general inventive concept) specifically describing the unique special technical feature in each group.

In the instant case, the Examiner did list the different claim groupings, but failed to explain why there is a lack of unity of invention among the various groups.

The Examiner asserted that dopaminergic cells used in the claimed methods could have been obtained by methods other than as claimed in Group I. The Examiner's argument disregards the fact that the claims are dependent on the method claims of Group I. It is not possible to carry out the method of a claim in Groups II, III or IV without using the invention as claimed in Group I, because all the claims include (through their dependence) the method steps in claim 1. Therefore, the Examiner's assertion, that dopaminergic cells used in those methods could have been obtained by other methods, is irrelevant. The Examiner's position is based on US restriction practice, and is not applicable to the instant case, in which unity of invention standards, and only those standards are applicable.

The Examiner also objected that methods of the other groups include additional special technical features not present in or required for the method of Group I. However, the presence of additional features in a dependent claim does not remove essential features from the claim. The recitation of additional features in the claims of Groups II, III and IV cannot negate the special technical features that are present

through their dependence on the Group I claims.

Further, in the rebuttal to applicant's traversal, the Examiner cited US Patent No. 6,284,539 as allegedly providing evidence that the dopaminergic cells of the instant invention are known in the prior art. The Examiner's action is procedurally improper, as this issue should have been addressed in the initial restriction requirement. In any event, the Examiner's position is without merit, considering that the cited reference neither teaches nor suggests the special technical feature of the instant invention, which is that a factor or factors obtainable from a Type 1 astrocyte of the ventral mesencephalon can be used to induce dopaminergic neuronal fate in a cell. The '539 patent cited by the Examiner does not even mention factors obtainable from Type 1 astrocytes of the VM. The Examiner's assertion that the dopaminergic cells were known in the prior art does not warrant a finding of lack of unity of invention in this case, since, as set forth above, the special technical feature of the instant invention is novel, and all of the claims relate to this special technical feature.

Thus, the Examiner has improperly evaluated unity of invention, and incorrectly applied U.S. restriction practice to the instant national phase application.

3. Procedural Irregularity of Final Restriction Requirement

In the Office Action dated 16 July 2003, the Examiner modified the claim groupings of the restriction requirement. Claims 33 and 36 had previously been assigned to Group I by the Examiner, and Group I was elected. In the July 16 Office Action, claims 33 and 36 were removed from Group I, and the restriction requirement was made final.

Claims 33 and 36 ostensibly depend from claim 22. A

cursory review of the pending claims shows that this is clearly a typing error and that claim 33 evidently should depend from claim 32, not 22. Claim 36 depends from claim 33. Therefore, both claims properly belong in "Group I", according to the Examiner's restriction requirement. Applicants will attend to this amendment in their next response.

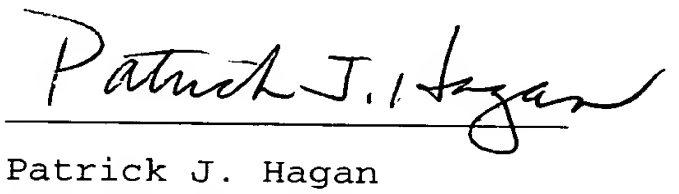
III. Action Requested

Applicants respectfully request that all claims be rejoined with Group I for examination, because they have unity of invention for the reasons stated above.

If any fee is required to be submitted in connection with this petition, the Commissioner is hereby authorized to charge such fee to the account of the undersigned attorneys, Deposit Account No. 04-1406. A duplicate copy of this paper is enclosed.

DANN DORFMAN HERRELL and
SKILLMAN, P.C.

Attorneys for Applicant

By 

Patrick J. Hagan
Registration No. 27,643

PJH:JEL